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60/179,065	31 January 2000 (31.01.2000)	US
60/180,628	4 February 2000 (04.02.2000)	US
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[Continued on next page]

WO 01/55312 A2

(54) Title: NUCLEIC ACIDS, PROTEINS, AND ANTIBODIES

(57) Abstract: The present invention relates to novel fetal tissue related polynucleotides and the polypeptides encoded by these polynucleotides herein collectively known as "fetal tissue antigens", and the use of such fetal tissue antigens for detecting disorders of the fetal tissues, particularly the presence of cancer and cancer metastases. More specifically, isolated fetal tissue associated nucleic acid molecules are provided encoding novel fetal tissue associated polypeptides. Novel fetal tissue polypeptides and antibodies that bind to these polypeptides are provided. Also provided are vectors, host cells, and recombinant and synthetic methods for producing human fetal tissue associated polynucleotides and/or polypeptides. The invention further relates to diagnostic and therapeutic methods useful for diagnosing, treating, preventing and/or prognosing disorders related to fetal tissue and/or proliferating cells, including cancer, and therapeutic methods for treating such disorders. The invention further relates to screening methods for identifying agonists and antagonists of polynucleotides and polypetides of the invention. The present invention further relates to methods and/or compositions for inhibiting the production and function of the polypeptides of the present invention.

60/236,327	29 September 2000 (29.09.2000)	US
60/236,370	29 September 2000 (29.09.2000)	US
60/236,368	29 September 2000 (29.09.2000)	US
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60/251,030	5 December 2000 (05.12.2000)	US
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(71) **Applicant** *(for all designated States except US)*: **HUMAN GENOME SCIENCES, INC.** [US/US]; 9410 Key West Avenue, Rockville, MD 20850 (US).

(72) **Inventors; and**

(75) **Inventors/Applicants** *(for US only)*: **ROSEN, Craig, A.** [US/US]; 22400 Rolling Hill Lane, Laytonsville, MD 20882 (US). **BARASH, Steven, C.** [US/US]; 111 Watkins Pond Blvd. #301, Rockville, MD 20850 (US). **RUBEN, Steven, M.** [US/US]; 18528 Heritage Hills Drive, Olney, MD 20832 (US).

(74) **Agents: HOOVER, Kenley, K.** et al.; Human Genome Sciences, Inc., 9410 Key West Avenue, Rockville, MD 20850 (US).

(81) **Designated States** *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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(74) **Agents: HOOVER, Kenley, K.** et al.; Human Genome Sciences, Inc., 9410 Key West Avenue, Rockville, MD 20850 (US).

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(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07H 21/02, 21/04; C07K 1/00, 14/00, 17/00
US CL : 536/23.1, 23.4; 530/350

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 536/23.1; 530/350

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
GeneBank, EMBL, Geneseq, EST, Issued Patents, SPTREMBL, SwissProt, PIR

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5994119 A (DIETZ) 30 NOVEMBER 1999, see SEQ ID NO:3.	1
A	US 5,700,674 A (KOYAMA et al.) 23 DECEMBER 1997, see SEQ ID NO:1.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Teresa Strzelecka Telephone No. (703) 308-0196

TERRY J. DEY
PARALEGAL SPECIALIST
TECHNOLOGY CENTER 1600

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/01321

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

1. Groups 1-886, claim(s) 1-10, 14, 15 and 21, all in part, drawn to an isolated polynucleotide of SEQ ID NO X encoding a peptide of SEQ ID NO NO: Y, wherein X and Y are values that correlate to those listed in Table 1A, and correspond to one of the cDNA Clone Ids, respectively. For example,

If group I is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1A, wherein X is 11 and Y is 911.

If group 2 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein X is 12 and Y is 912.

2. Groups 887-1772, claim(s) 11, 12, 16 and 23, all in part, each group directed to a polypeptide of SEQ ID NO; Y, wherein Y correlates to one of those listed in Table 1A, and corresponds to one of the cDNA Clone IDs, respectively. For example,

If group 887 is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1A, wherein Y is 911.

If group 888 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein Y is 912.

3. Groups 1773-2658, claim 13, in part, drawn to an isolated antibody which binds to a protein with SEQ ID NO Y, wherein Y correlates to one of those listed in Table 1A, and corresponds to one of the cDNA Clone IDs, respectively. For example,

If group 1773 is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1A, wherein Y is 911.

If group 1774 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein Y is 912.

4. Groups 2659-3544, claim 17, in part, drawn to a method for preventing, treating or ameliorating an undefined medical condition by administering a polynucleotide of SEQ ID NO X, wherein X correlates to one of those listed in Table 1A, and corresponds to one of the cDNA Clone IDs, respectively. For example,

If group 2659 is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1A, wherein X is 11.

If group 2660 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein X is 12.

5. Groups 3545-4430, claims 18 and 19, in part, drawn to a method of diagnosis of an undefined pathological condition by determining the presence or absence of a mutation in a polynucleotide of SEQ ID NO X, wherein X correlates to one of those listed in Table 1A, and corresponds to one of the cDNA Clone IDs, respectively. For example,

If group 3545 is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1A, wherein X is 11.

If group 3546 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein X is 12.

6. Groups 4431-5316, claim 20, in part, drawn to a method of identifying a binding partner to a polypeptide defined by SEQ ID NO Y, wherein Y correlates to one of those listed in Table 1A, and corresponds to one of the cDNA Clone IDs, respectively. For example,

If group 4431 is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1A, wherein Y is 911.

If group 44322 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein Y is 912.

7. Groups 5317-6202, claim 22, in part, drawn to a method of identifying an activity in a biological assay by identification of the protein in the supernatant wherein the cell expresses a polypeptide encoded by SEQ ID NO X, wherein X correlates to one of those listed in Table 1A, and corresponds to one of the cDNA Clone IDs, respectively. For example,

If group 5317 is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1A, wherein X is 11.

If group 5318 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein X is 12.

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8. Groups 6203-7088, claim 24, in part, drawn to a method for preventing, treating or ameliorating an undefined medical condition by administering a polypeptide of SEQ ID NO Y, wherein Y correlates to one of those listed in Table 1A, and corresponds to one of the cDNA Clone IDs, respectively. For example,

If group 6203 is elected, this correlates to Gene no 1, cDNA clone ID HE2AC66 of Table 1, wherein Y is 911.
If group 6204 is elected, this correlates to Gene No 2, cDNA clone ID HE2A012, wherein Y is 912.

The inventions listed as Groups 1-7088 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The polynucleotides and polypeptides of each invention are unrelated, each to each other. Where, for example, claim 1, items (e) through (f) do not require a polynucleotide of any degree of specificity to a sequence, it is apparent that Lindeskog et al. (1999, Virology Vol 258(2) 441-450) discloses a DNA encoding a polypeptide wherein said DNA renders claim 1, among the other, not novel. Thus the technical feature of the polynucleotide sequence is not special and the groups are not so linked under PCT Rule 13.1. Additionally the claimed methods produce different products and/or different results which are not coextensive and which do not share the same technical feature.

INTERNATIONAL SEARCH REPORT

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Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1 (in part), SEQ ID NO:11 and 911

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

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[Continued on next page]

WO 01/55312 A2

(54) Title: NUCLEIC ACIDS, PROTEINS, AND ANTIBODIES

(57) Abstract: The present invention relates to novel fetal tissue related polynucleotides and the polypeptides encoded by these polynucleotides herein collectively known as "fetal tissue antigens", and the use of such fetal tissue antigens for detecting disorders of the fetal tissues, particularly the presence of cancer and cancer metastases. More specifically, isolated fetal tissue associated nucleic acid molecules are provided encoding novel fetal tissue associated polypeptides. Novel fetal tissue polypeptides and antibodies that bind to these polypeptides are provided. Also provided are vectors, host cells, and recombinant and synthetic methods for producing human fetal tissue associated polynucleotides and/or polypeptides. The invention further relates to diagnostic and therapeutic methods useful for diagnosing, treating, preventing and/or prognosing disorders related to fetal tissue and/or proliferating cells, including cancer, and therapeutic methods for treating such disorders. The invention further relates to screening methods for identifying agonists and antagonists of polynucleotides and polypetides of the invention. The present invention further relates to methods and/or compositions for inhibiting the production and function of the polypeptides of the present invention.

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(71) **Applicant** *(for all designated States except US)*: **HUMAN GENOME SCIENCES, INC.** [US/US]; 9410 Key West Avenue, Rockville, MD 20850 (US).

(72) **Inventors; and**

(75) **Inventors/Applicants** *(for US only)*: **ROSEN, Craig, A.** [US/US]; 22400 Rolling Hill Lane, Laytonsville, MD 20882 (US). **BARASH, Steven, C.** [US/US]; 111 Watkins Pond Blvd. #301, Rockville, MD 20850 (US). **RUBEN, Steven, M.** [US/US]; 18528 Heritage Hills Drive, Olney, MD 20832 (US).

(74) **Agents: HOOVER, Kenley, K.** et al.; Human Genome Sciences, Inc., 9410 Key West Avenue, Rockville, MD 20850 (US).

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